K101224

Griffiths and Nielsen Ltd.
Traditional 510(k)

For the SaphenaMEDICAL® Anti -Embolism Stocking

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Griffiths and Nielsen Ltd

Submitter's Address:

DEC 3 2010

Griffiths and Nielsen Ltd
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Establishment Registration Number:

Still to be obtained

Contact Person:

Edwin Lindsay

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Date Prepared:

8th November 2010

K10224

Griffiths and Nielsen Ltd.
Traditional 510(k)

For the SaphenaMEDICAL® Anti -Embolism Stocking
510(k) Summary

Device Classification Information:

Regulation Number	Device Name	Device Class	Product Code	Classification Panel
880.5780	Stocking, Medical Support (To Prevent Pooling of Blood In Legs)	Class 2	DWL	General Hospital

Device Trade Name:

Anti-Embolism Stockings

Device Common Name:

SaphenaMEDICAL Anti-Embolism Stockings

Intended Use/Indications for Use:

SaphenaMEDICAL Anti-Embolism Stockings are intended to:

- Help to prevent the pooling of blood in the legs by applying controlled pressure to the legs.
- Help to prevent Deep Vein Thrombosis (DVT) and, edema and leg discomfort in individuals subjected to immobility.

Summary of Substantial Equivalence:

The SaphenaMEDICAL Anti-Embolism Stockings are substantially equivalent to the following predicate devices with respect to the intended use/indications for use, and the technological characteristics:

Company Name	Product Details	510(k) Number
Beiersdorf INC.	Anti-Embolism Stockings	K090921
Knit-Rite, INC.	Therafirm Anti-Embolism Stockings	K091141
KENDALL, a division of Tyco Healthcare Group LP	Kendall T.ED. Anti-Embolism Stockings	K925417
Carolon CO	CAP anti-embolism stockings	Approved Prior to 510k Requirement – Grandfathered

The SaphenaMEDICAL Anti-Embolism Stockings and their substantial equivalents, mentioned above, are knit on circular knit machines with nylon and spandex. They all include knee-high and thigh-high styles. The knee-high is sized based on ankle and calf circumferences, while the thigh-high is sized based on ankle, calf, and thigh circumference fit.

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For the SaphenaMEDICAL® Anti -Embolism Stocking
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Device Description:

SaphenaMEDICAL Anti-Embolism Stockings are ready-to-wear for post-operative/ surgical, reclining or bed-confined patients, to help prevent pooling of blood and fluid in the extremities by applying controlled graduated pressure. The fabric used is comprised of nylon and lycra which is used in the predicate devices.

The SaphenaMEDICAL Anti-Embolism Stockings provide controlled, uniform graduated compression, as is provided in all of these substantially equivalent products, starting with more compression circumferentially at the ankle at approximately 18 mmHg (based on average ankle size) then gradually decreases up to the proximal end. (14mmHg at the mid-calf and 8mmHg at the upper thigh)

Compression for the SaphenaMEDICAL Anti-Embolism Stockings, as well as all the predicate devices, is provided by lycra that acts circumferentially on the extremity. The gradient compression present in these products helps reduce capillary leakage and improve capillary and lymphatic drainage and/or absorption. Consequently, they can be used to manage the same indications, i.e. edema and lymphedema.

The Anti-Embolism Stockings are not made with natural rubber latex.

Technological Characteristics:

A comparative review of the SaphenaMEDICAL Anti-Embolism Stockings with the predicate devices found that the technological characteristics, performance and principle of operation were substantially equivalent.

A comparison is presented in the table below:

Property	New Device: SaphenaMEDICAL Anti-Embolism Stockings	Anti-Embolism Stockings	Therafirm Anti-Embolism Stockings	Kendall T.ED. Anti-Embolism Stockings	CAP anti-embolism stockings
Device Manufacturer	Griffiths and Nielsen Ltd	Beiersdorf INC.	Knit-Rite, INC.	KENDALL, a division of Tyco Healthcare Group LP	Carolon CO
Device Trade / Common Name	SaphenaMEDICAL Anti-Embolism Stockings	Anti-Embolism Stockings	Therafirm Anti-Embolism Stockings	Kendall T.ED. Anti-Embolism Stockings	CAP anti-embolism stockings
510(K) Number	N/A	K090921	K091141	K925417	Approved Prior to 510k Requirement – Grandfathered
Device Classification name	Stocking, Medical Support (To Prevent Pooling of Blood In Legs)	Stocking, Medical Support (To Prevent Pooling of Blood In Legs)	Stocking, Medical Support (To Prevent Pooling of Blood In Legs)	Stocking, Medical Support (To Prevent Pooling of Blood In Legs)	Stocking, Medical Support (To Prevent Pooling of Blood In Legs)

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Property	New Device: SaphenaMEDICAL Anti-Embolism Stockings	Anti-Embolism Stockings	Therafirm Anti-Embolism Stockings	Kendall T.E.D. Anti-Embolism Stockings	CAP anti-embolism stockings
Device Classification	Class II	Class II	Class II	Class II	Class II
Prescription or Over the Counter	Over the Counter	Over the Counter	Over the Counter	Over the Counter	Over the Counter
Materials	Nylon and spandex (elastane /lycra)	Nylon and spandex (elastane /lycra)	Nylon and spandex (elastane /lycra)	Nylon and spandex (elastane /lycra)	Nylon and spandex (elastane /lycra)
Sizes	Small, Medium, Large, Extra Large	Small, Medium, Large, Extra Large, Extra (x2) Large	Small, Medium, Large, Extra Large, Extra (x2) Large	Small, Medium, Large, Extra Large	Small, Medium, Large, Extra Large
Intended Use	Anti-Embolism Stockings are to help prevent edema, leg discomfort, and deep vein thrombosis or individuals subjected to immobility.	Anti-Embolism Stockings are to help prevent edema, leg discomfort, and deep vein thrombosis or individuals subjected to immobility.	Anti-Embolism Stockings are to help prevent edema, leg discomfort, and deep vein thrombosis or individuals subjected to immobility.	Anti-Embolism Stockings are to help prevent edema, leg discomfort, and deep vein thrombosis or individuals subjected to immobility.	Anti-Embolism Stockings are to help prevent edema, leg discomfort, and deep vein thrombosis or individuals subjected to immobility.
Intended Location of Use	Below the knee and thigh-high stockings	Below the knee and thigh-high stockings	Below the knee and thigh-high stockings	Below the knee and thigh-high stockings	Below the knee and thigh-high stockings
Device Description	The Anti-Embolism Stockings are designed for the post-operative/ surgical , reclining or bed-confined patients	The Anti-Embolism Stockings are designed for the post-operative/ surgical , reclining or bed-confined patients	The Anti-Embolism Stockings are designed for the post-operative/ surgical , reclining or bed-confined patients	The Anti-Embolism Stockings are designed for the post-operative/ surgical , reclining or bed-confined patients	The Anti-Embolism Stockings are designed for the post-operative/ surgical , reclining or bed-confined patients
Compression Levels	10-20 mmHg	10-20 mmHg	10-20 mmHg	10-20 mmHg	10-20 mmHg

Performance Data:

The Anti-Embolism products being submitted are substantially equivalent to the predicate product in material content, function and indication bench testing demonstrated that the safety and effectiveness of the SaphenaMEDICAL Anti-Embolism Stockings is equivalent to the predicate devices.

This statement is to assure that SaphenaMEDICAL Anti-Embolism Stockings are safe and effective when worn for their intended purpose and fit properly according to the guidelines.

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See Section 18 on Performance Testing - Bench for nonclinical testing that demonstrates that the device is safe, effective, and performs in comparison to predicate devices.

Safety and Effectiveness:

The SaphenaMEDICAL Anti-Embolism Stockings utilises similar technology currently found in legally marketed predicate devices. Based on testing and comparison with the predicate devices, the SaphenaMEDICAL Anti-Embolism Stockings indicated no adverse indications or results. It is our determination that the SaphenaMEDICAL Anti-Embolism Stockings are safe, effective and performs within its design specifications and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Edwin Lindsay
Quality and Regulatory Specialist
Griffiths and Nielsen Limited
Stane Street, Slinfold
Horsham, West Sussex
United Kingdom RH13 0TW

DEC - 3 2010

Re: K101224
Trade/Device Name: SaphenaMEDICAL® Anti-Embolism Stocking
Regulation Number: 21 CFR 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: November 8, 2010
Received: November 15, 2010

Dear Mr. Lindsay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

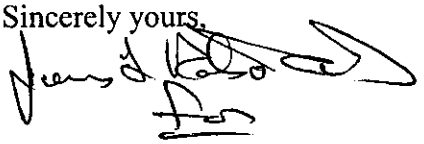
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Traditional 510(k)
For the SaphenaMEDICAL® Anti -Embolism Stocking

DEC - 3 2010

Indications for Use

510(k) Number (if known): K101224

Device Name: SaphenaMEDICAL® Anti -Embolism Stocking

Indications for Use:

SaphenaMEDICAL Anti-Embolism Stockings are intended to:

- Help to prevent the pooling of blood in the legs by applying controlled pressure to the legs.
- Help to prevent Deep Vein Thrombosis (DVT) and also edema and leg discomfort, individuals subjected to immobility.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101224